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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/138,735	08/24/98	PARANHOS-BACCALA G	WPB-36400B

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OLIFF & BERRIDGE
P O BOX 19928
ALEXANDRIA VA 22320

EXAMINER	
GRASER, J	
ART UNIT	PAPER NUMBER
1641	6

DATE MAILED: 04/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/138,735	Parahnos-Baccala
Examiner	**Group Art Unit**
Graser, Jennifer	1641

☒ Responsive to communication(s) filed on *Response to Notice to Comply* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number) *08/480,917* .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear what is encompassed by a nucleic acid which is "equivalent" to a nucleotide sequence starting at nucleotide 1232 and ending at nucleotide 1825 of SEQ ID NO:1'. How is this sequence 'equivalent"? Is it identical structurally or does it have an identical function? Additionally, the word "fully" should be inserted before the word 'complementary" in order to avoid reading on one nucleotide.

Claim 2 is vague and indefinite because it is unclear how the first sequence of claim 1 and the second sequence of claim 2 are related. Are there two different fragments being claimed? Claim 2 is broader than claim 1 and does not further limit the first claim because it is claiming a larger fragment, i.e., nucleotides 1232-2207 of SEQ ID NO:1 instead of 1232-1825 of SEQ ID NO:1 as recited in claim 1. The way the claim is written it makes it seem as if there are two different fragments yet it seems that Applicants just intend to claim a larger piece of the fragment of claim 1. Clarification is requested.

Additionally, claim 2 is vague and indefinite because it is unclear what is encompassed by a nucleic acid which is "equivalent" to a nucleotide sequence starting at nucleotide 1232 and ending at nucleotide 2207 of SEQ ID NO:1'. How is this sequence 'equivalent"? Is it identical or have an identical function? Additionally, the word "fully" should be inserted before the word 'complementary" to avoid reading on one nucleotide.

Claims 3 and 4 are vague and indefinite due to the recitation of a "correspondingly long segment of the sequence identified in SEQ ID NO:1" because it is unclear what is considered a correspondingly long segment. These claims are vague and indefinite as they call for any 30 nucleotide segment of a segment comprising 1232-2207 of SEQ ID NO:1 or 1232-1825 of SEQ ID NO:1, to be only 50% homologous with any segment of SEQ ID NO:1. A 30 nucleotide segment which is at least 50% homologous with a segment of SEQ ID NO:1 allows for numerous differences between the sequence and it is unclear if this is what Applicants intend.

Claims 5-7 are vague and indefinite because it is unclear what is encompassed by the term "hybridizable". Specifically, what are the conditions of the hybridization, i.e., high stringency, low, medium, etc.? The exact conditions of hybridization should be included in the claim. Additionally, in claim 5 it is unclear what is meant by "at least a segment of a nucleic acid according to claim 1", i.e., is a segment 1, 2, 5 ,10, 100... nucleotides?

Claim 8 is vague and confusing because the hybridization conditions are not recited in the claim. Further, the nucleotide sequence of the primer is not adequately defined, i.e., how many nucleotides are required for amplification and which ones?

Claim 10 is vague and indefinite because it recites a primer according to claim 9 which is selected from a group of sequences which ultimately depend on claim 1 and claim 1 recites fragments which start at nucleotide 1232 and end at nucleotide 1825 of SEQ ID NO:1, their complements, equivalents, etc.. However, some of the sequences recited in instant claim 10 do not fall anywhere within the range of nucleotides of 1232-1825 of SEQ ID NO:1 nor do they correspond to this range of the sequence and therefore it is unclear how they would "hybridize to a segment of a nucleic acid according to claim 1" as required by the claim. Specifically, SEQ ID NO:7 is not from SEQ ID NO:1, but instead corresponds to a 5' end of the mRNAs in trypanosomatides, called a spliced leader and are taught by Parsons et al. 1984; see specification page 23, lines 20-25. Further, SEQ ID Nos:10 and 12 lie outside of the range of SEQ ID NO:1, e.g., SEQ ID NO: 10 consists of nucleotides 2187-2207 and SEQ ID NO: 12 consists of nucleotides 1997-2017. Therefore, it is not understood how these sequences or their complements could hybridize to nucleotides 1232-1825 of SEQ ID NO:1. Clarification and correction is requested.

Claim 11 is vague and indefinite because it is unclear whether or not Applicants intend to claim a capture probe or a detection probe. The language of "if they are both present" is vague and confusing and amounts to "optional" language. It is generally viewed that if an ingredient is optional, it does not belong in the claim. Additionally, it is unclear what is encompassed by "at least partially different". The degree of difference cannot be understood, i.e., is this one

nucleotide difference, 5, 10, 15 etc... Further, the claim is vague and indefinite because the hybridization conditions are not recited in the claim.

Claim 17 is vague and indefinite because it is unclear whether or not the primer is intended to be different from the capture or detection probes recited in claim 11. Further, the claim is vague and indefinite because it is unclear what is encompassed by a nucleic acid which is "equivalent" to a nucleotide sequence starting at nucleotide 1232 and ending at nucleotide 1825 of SEQ ID NO:1'. How is this sequence 'equivalent"? Is it identical or have an identical function? Additionally, the word "fully" should be inserted before the word 'complementary" to avoid reading on one nucleotide. Lastly, the claim is vague and indefinite because the hybridization conditions are not recited in the claim.

Claim 20 is vague and indefinite because it is unclear what is encompassed by the term "hybridization". Specifically, what are the conditions of the hybridization, i.e., high stringency, low, medium, etc.? Further, the claim is vague and indefinite because it is unclear what is encompassed by a nucleic acid which is "equivalent" to a nucleotide sequence starting at nucleotide 1232 and ending at nucleotide 1825 of SEQ ID NO:1'. How is this sequence 'equivalent"? Is it identical or have an identical function? Additionally, the word "fully" should be inserted before the word 'complementary" to avoid reading on one nucleotide. Lastly, the claim is vague and indefinite because the hybridization conditions are not recited in the claim.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

> person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The breadth of the instant claims contain nucleotide sequences other than what is specified in the sequence disclosure. The specification states that substitutions, additions, or deletions may be made to the defined sequences; however, the specification provides no guidance as to what nucleotides may be changed without causing a detrimental effect to the protein to be produced or its ability to function as a probe or primer. Further, it is unpredictable as to which nucleotides could be removed and which could be added. Claims 3 and 4 recite nucleic acid fragments which are "at least an 30 nucleotide segment of [SEQ ID NO: 1, 1232-1825;1232-2207] is at least 50% homologous with a correspondingly long segment of the sequence identified as SEQ ID NO:1". It is unclear what sequence this encompasses and what function it would serve. One can see from the art rejections provided below that a provides for numerous gaps, inclusions and differences. It does not appear that the sequences as claimed in claims 3 and 4 would be able to function as probes or primers as they would pick up numerous sequences which are not even in anyway related to the sequences of the invention. In fact the nucleotide sequences these fragments can detect pick up nucleic acids from completely different organisms. Applicants

have not taught the scope recited in claims 3 and 4. Given the lack of guidance contained in the specification and the unpredictability for determining acceptable nucleotide substitutions, one of skill in the art could not make or use the broadly claimed invention without undue experimentation.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-9, 11 and 17 are rejected under 35 U.S.C. 102(b)/(a) as being anticipated by any one of Ko et al (Gencore Accession # M30933, 1990) and Opperman et al (Gencore Accession # L27277 from J.Bacteriol. 1994. 176(16): 5033-5043).

Ko et al. and Opperman et al. both disclose a sequence which is complementary to SEQ ID NO: 1, nucleotides 1232 and 1825 and nucleotides 1232-2207 of SEQ ID NO: 1 because the instant claims do not require the sequence to be fully complementary. Additionally, the sequences disclosed by Ko and Opperman have at least 30 nucleotides and are at least 50% homologous to a segment of SEQ ID NO:1. See Best local similarity attached sequence alignment. These sequences also would hybridize under low conditions to SEQ ID NO:1 and they comprise between 5 and 100 nucleotides.

7. Claims 1, 2, 5, 6, 7, 8, 9, 10, 11 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by any one of Porteus et al (Gencore Accession # JH0465, 1991) and Pentecost (Gencore Accession #P07746, 1985)

Porteus et al disclose a sequence which has 100% best local similarity and 82% overall similarity to SEQ ID NO:8 (nucleotides 1442-1459 of SEQ ID NO:1). This sequence falls within the range recited in instant claims 1 and 2 and would be complementary. The sequence also comprises 8 nucleotides which falls within the ranges for the probes recited in claims 6 and 7. See attached sequence alignments.

Penecost disclose nucleic acid sequences comprising 10 nucleotides which is 90% similar to SEQ ID NO: 8 and SEQ ID NO:9 (nucleotides 1266-1287 of SEQ ID NO:1). These sequences fall within the range recited in instant claims 1 and 2 and would be complementary. The sequence also comprises 8 nucleotides which falls within the ranges for the probes recited in claims 6 and 7. See attached sequence alignments.

There were also numerous hits on SEQ ID Nos: 7, 10 and 12, but since these sequences do not fall within the ranges required by the claims they were not included in the rejection. See the 112, second paragraph rejection of claim 10 above.

8. Claims 12-16 and 18-20 are objected to as being dependent upon a rejected base claim. No claims are allowed.

9. Correspondence regarding this application should be directed to Group Art Unit 1641. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The

faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1641 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jennifer Graser 4/6/00
JENNIFER GRASER
PATENT EXAMINER